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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/629,380	VANDEZANDE, KIRK EDWARD	
	Examiner	Art Unit	
	Shubo (Joe) Zhou	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *9/19/07, 5/15/07*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-14 and 19-21* is/are pending in the application.

4a) Of the above claim(s) *19-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendments/Arguments

As pointed out in the Notice of Noncompliant Amendment mailed 8/1/07, in view of the multiple noncompliant amendments filed, what had been entered were the amendments to the claims filed 2/2/07 and 5/15/07, respectively, but none of the amendments to the specification including the substitute specification filed therebefore had been entered. In the response filed 9/19/07, applicant filed amendment to the specification, which is entered, but did not file a substitute specification, it is the Office's interpretation that applicant did not intend to file a compliant substitute specification. Thus, what is based on in this action is the originally filed specification with the various entered amendments.

It is noted that claims 19-21 are newly added. However, the invention of the new claims 19-21 and the elected invention of claims 1-2 and 4-14 are directed to related but patentably distinct processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the methods of elected claims 1-2 and 4-14 and the methods of new claims 19-21 are related because they are both directed to methods involving determining the optimal test order for diagnosing mutations that relate to a disease. However they are distinct because they comprise distinct steps. The invention of the elected claims 12-14 (the method claims) involves a) receiving data

indicative of a historical frequency distribution of mutations that relate to the disease and the assays required to diagnose the mutations that relate to the disease; b) creating a history database, the database comprising a sequence of records based on the data; c) receiving new data indicative of the historical frequency distribution of mutations that relate to the disease and the assays required to diagnose the mutations that relate to the disease; d) applying at least one decision tree algorithm, wherein the at least one decision tree algorithm scores at least a portion of the new data; and e) generating a recommendation if the score satisfies a threshold. The invention of new claims 19-21, however, involves a) generating a data set comprised of data obtained by: identifying a spectrum of mutations that relate to the disease and the frequency with which each mutation occurs in the population; for each mutation in the population, identify a set of assays that provide a diagnosis; for each assay, identifying the average cost of each assay; and for each assay performed, identifying the probability of a successful diagnosis wherein the probability of a successful diagnosis is the benefit of the diagnosis; b) maintaining the data set to include new data received on the spectrum of mutations that relate to the disease, the frequency with which each mutation occurs in the population and the set of assays that provide a diagnosis; (c) applying at least one decision tree algorithm to the data, wherein the at least one decision tree algorithm comprises: (i) generating at least two strategies using the assays within the data set; (ii) ranking the at least two strategies by calculating the strategy expected cost of the at least two assays, wherein the strategy expected cost is determined using a particular mathematical formula as specifically set forth in the claim; and (iii) identifying, from the ranked at least two strategies, the at least one strategy with the lowest strategy expected cost.

Clearly the method of new claims 19-21 and that of elected claims 12-14 (and the computer program and system therefor) are mutually exclusive, not obvious variants and have different modes of actions, functions and effects.

Therefore, claims 19-21 are withdrawn from further consideration as being drawn to nonelected invention.

Consequently, claims 1-2, 4-14 and 19-21 are currently pending, but only claims 1-2 and 4-14 are under consideration.

Applicant's arguments filed 5/15/07 in response to the previous Office action mailed 7/21/06 have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections are either reiterated from the previous Office action or newly applied but necessitated by applicant's amendments, and constitute the complete set presently being applied to the instant application. Rejections and/or objections set forth in the previous Office action but not reiterated herein are hereby withdrawn.

Specification

The specification is objected to because of the following:

It is noted that an Office letter was mailed on 10/27/03 requiring a substitute specification in compliance with 37 CFR 1.52, 1.121(b)(3) and 1.125. In response, applicant filed a substitute specification on 12/23/03. However, the substitute specification filed is not in compliance with 37 CFR 1.52, 1.121(b)(3) and 1.125. Firstly, 37 CFR 1.121(b)(3) requires that a substitute specification be filed "by submitting an instruction to replace the specification." The response

filed 12/23/03 does not include such instruction. Secondly, 37 CFR 1.125(b) requires that a substitute specification may be filed "if it is accompanied by a statement that the substitute specification includes no new matter." The response filed 12/23/03 does not include such statement. As such, a substitute specification in complete compliance with 37 CFR 1.52, 1.121(b)(3) and 1.125 is still required.

This is reiterated from the previous Office action mailed 7/31/06. As set forth in the first paragraph of the present action, the various substitute specifications filed after the mailing of the previous Office action on the merits (7/31/06) have not been entered due to noncompliance with 37 CFR 1.121.

Appropriate correction is required.

Claim Rejections-35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-2 and 4-14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

This rejection is reiterated from the previous Office action.

The claims are drawn to a process or a computer readable medium comprising computer executable instructions to perform the process or a system for performing the process, for determining an optimal test order for diagnosing mutations related to a disease. The process

comprises receiving data, creating a database, receiving new data, applying a decision tree algorithm and generating a recommendation.

Since the invention involves mathematical algorithm, a judicial exception to statutory subject matter, the following analysis of facts of this particular patent application follows the rationale suggested in the "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (OG Notices: 22 November 2005, available from the US PTO website at http://www.uspto.gov/web/offices/com/sol/og/2005/week47/og200547.htm, a copy of which is enclosed herein).

The Guidelines states:

> *To satisfy section 101 requirements, the claim must be for a practical application of the § 101 judicial exception, which can be identified in various ways (Guidelines, p. 19):*
>
> *- The claimed invention "transforms" an article or physical object to a different state or thing.*
> *- The claimed invention otherwise produces a useful, concrete and tangible result, based on the factors discussed below.*

In the instant case, the claimed invention is a process of manipulating and converting data in a computational device and does not transform an article or physical object to a different state or thing outside a computation device.

Furthermore, the invention does not produce a useful, concrete and tangible result. Specifically it does not produce a tangible and useful result. While the last step of the process generates a recommendation, it does not include particular substance. Since it is not clear as to what the recommendation is about, such a process appears to be an abstract idea rather than a practical application of the idea because it does not produce a tangible result. Furthermore, the

final result is not used or made available to be used. As to claims 1-2 and 4-11, drawn to computer readable medium comprising instructions and system for performing the method process, since the method process is nonstatutory as not producing a useful, concrete and tangible result, a computer readable medium comprising instructions and system for performing the method process are nonstatutory for the same reasons. Additionally, it is recognized in the art that computer readable medium could include carrier wave, which is a signal and nonstutory, at least one embodiment of claims 1 and 2 is nonstatutory as being drawn to a signal.

Moreover, the amended claims 4-11 are drawn to a system that appears to be a hybrid of a product and a process. While a), b) and d) and e) appear to be components or structural parts of the system, which thus appears to be a product, newly added e) is "receiving data," which is a step of a process. The claims are nonstatutory because they are directed to neither a "process" nor a "product", but rather embrace or overlap two different statutory classes of inventions. See MPEP, 2173.05(p)II.

Applicant's argument filed 5/15/07 has been fully considered but it is not persuasive. The argument is on the ground that the amendment to the claims overcomes the rejection but applicant fails to provide detailed argument. See page 11 of the response. This is not persuasive because the amended claims still do not either achieve a physical transformation or produce a useful, concrete and tangible result for the same reasons set forth above. As a matter of fact, that is added reasons for being nonstatutory for amended claims 4-11 as they appear to embrace or overlap two different statutory classes of inventions.

Claim Rejections-35 USC § 112

The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As set for the above, amended claims 4-14 appear to embrace or overlap two different statutory classes of inventions, the claims are thus indefinite for the following reasons:

MPEP 2173.05(p) states:

> *II. PRODUCT AND PROCESS IN THE SAME CLAIM*
>
> *A single claim which claims both an apparatus and the method steps of using the apparatus is indefinite under 35 U.S.C. 112, second paragraph. In Ex parte Lyell, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990), a claim directed to an automatic transmission workstand and the method steps of using it was held to be ambiguous and properly rejected under 35 U.S.C. 112, second paragraph.*
> *Such claims should also be rejected under 35 U.S.C. 101 based on the theory that the claim is directed to neither a "process" nor a "machine," but rather embraces or overlaps two different statutory classes of invention set forth in 35 U.S.C. 101 which is drafted so as to set forth the statutory classes of invention in the alternative only. Id. at 1551.*

The preambles of the claims, e.g. that of claim 12, recite a method for determining the optimal test order for diagnosing mutations. However, the process steps do not produce such an optimal test order. While step e) of claim 12 generates "a recommendation," it is not clear what the recommendation is about.

Clarification of the metes and bounds of the claims is requested.

Claim Rejections-35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4-14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Bapat et al. (Gut, Vol 44, pages 698-703, 1999).

In light of the indefiniteness of the claims as set forth above, the art is being applied to the best interpretation and understanding of the claims as written.

Claims 4-14 are drawn to a process comprising computer executable instructions to perform the process for determining an optimal test order. The process comprises receiving data, creating a database, receiving new data, applying a decision tree algorithm and generating a recommendation.

Bapat et al. disclose a method for cost comparison of different strategies for screening and diagnosing familial adenomatous polyposis (FAP) using decision tree to determine the optimal test. Bapat et al. presented research data since 1991 including clinical testing of FAP and analysis of mutations of the gene APC that relate to FAP. These data include such information as more than 90% of known germline APC mutations resulted in a truncated protein. Of these, 18% of the germline mutations occur at two mutation hot spot regions: codons 1061-1063 and 1309-

1311. See the paragraph bridging pages 698, right column and page 699, left column. Bapat et al. indicate that the frequency of common and novel mutations in 202 families were published in 1994. See page 699, left column, last paragraph and reference number 17 on page 703. All these data are interpreted as historical data indicative of the frequency distribution of mutations relating to a disease, as recited in the instant claims. Bapat et al. also disclose APC mutation distributions in different age groups as previously (historically) disclosed by others. See Table 1 on page 700. The compilation of these data of mutation distributions in the APC gene and in different patient age groups from research in the past is interpreted as a history database. Bapat et al. disclose that for evaluating the cost of identifying germline APC mutations, mutation testing are done with patients in Gastrointestinal Cancer Registry using molecular diagnostic technologies in the authors' laboratory. There were 124 FAP families that have been screened using these mutation analysis and truncating mutations are identified in 92 families. See page 699. These data is interpreted as the new data indicative of the frequency distribution of mutations relating to a disease, as recited in the instant claims. At least one decision tree algorithm is used in cost comparison analysis of the mutation testing strategy versus clinical screening strategy including the baseline model and sensitivity model. See page 700, Fig. 1. The decision analysis is based on information about the new data (see page 699, right column). In the decision analysis, a threshold is set as a point at which the two strategies have equal costs. See page 701. The cost obtained by decision analysis reveals a cost value at 252, satisfying the threshold value at 851. See Table 4 on page 701. The costs for each test as determined by the decision analysis are also projected in Table 4. The comparison by Bapat et al. also reveals that genetic testing approach, i.e. mutation analysis, costs about one third to one thirteenth less than

that of the conventional clinical strategy over a wide range of variables, which makes Bapat et al. recommend that "on the basis of economic variables alone, molecular genetic testing was the method of choice." See page 702, left column. As to the systems in claims 4-11, Bapat et al. disclose that their decision tree models are constructed and evaluated using the software program referred to as SMLTREE. Given that such a computer software was used, it would have been readily recognized by one skilled in the art that the computer using the software must have included an input device for receiving data, a computing environment, an output device and the software comprising the decision tree algorithm. Note that since claims 4-11 are drawn to systems comprising an input device "for receiving data" and an output device "for outputting data," the claims do not required actual actions of inputting data and outputting data.

Applicant's arguments filed 5/15/07 have been fully considered but they are not persuasive. Applicant argues that Bapat does not disclose each feature of the present invention. Specifically, Bapat does not disclose a cost-effective method of identifying the unique genetic mutation(s) that leads to colon cancer, or any other genetic disease, but takes as given the cost of such analysis. See page 15 of the response. This is not found persuasive because the instantly claimed method (claims 12-14) does not identify unique genetic mutations that lead to a disease. None of the steps, e.g. a) through e) of claim 12, requires identifying any mutation, let alone unique mutation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bapat et al. (Gut, Vol 44, pages 698-703, 1999).

The claims are drawn to a computer readable medium comprising computer executable instructions for performing a process for determining an optimal test order. The process comprises receiving data, creating a database, receiving new data, applying a decision tree algorithm and generating a recommendation.

As set forth for claims 4-14 above, Bapat et al. disclose such a process. However, they do not explicitly disclose a computer readable medium comprising computer executable instructions for performing the process.

In *In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958), the court held that broadly providing an automatic or mechanical means to replace a manual activity which accomplish the same result is not sufficient to distinguish over the prior art (see also *Manual of Patent Examining Procedure,* U.S. Trademark and Patent Office, section 2144.04, III).

In the instant case, the claimed invention merely makes the process of Bapat et al. as computer-implemented or automatic and indeed accomplishes the same result. It is thus not sufficient to distinguish over Bapat et al. Therefore, the claimed invention, i.e. the computer readable medium comprising instructions to execute a process would have been obvious to a person of ordinary skill in the art at the time the invention was made over the process disclosed by Bapat et al.

Furthermore, while Bapat et al. do not explicitly disclose such a computer medium comprising instructions for executing all the steps of the process as in claim 1, they do disclose that their decision tree models are constructed and evaluated using the software program referred to as SMLTREE. Thus they at least disclose a computer readable medium comprising instructions for executing at least steps c)-e) as in claim 1, i.e. the steps of receiving data, applying the decision tree algorithm and generating recommendation. Thus, the entire method of Bapat et al. could be interpreted as semi-automatic. One of ordinary skill in the art would have been motivated to make it completely automatic by comprising instructions in the computer readable medium for executing the steps of a) and b) to take the obvious advantage of a fully automatic process, i.e. saving time and cost.

There would have been a reasonable expectation of success because the court held regarding software that "writing code for such software is within the skill of the art, not requiring undue experimentation, once its functions have been disclosed." Fonar Corp., 107 F.3d at 1549, 41 USPQ2d at 1805.

Applicant's arguments filed 5/15/07 have been fully considered but they are not persuasive. The argument is on the ground that Bapat et al. do not disclose a method of determining a minimal cost test order for diagnosing mutations. This is not found persuasive because neither the method claims (12-14) nor the system and computer readable medium claims (1-2 and 4-11) requires determining a minimal cost test order for diagnosing mutations (note the underlined word).

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a).

Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. §1.136 (a). A shortened statutory period for response to this final action is set to expire three months from the date of this action. In the event a first response is filed within two months of the mailing date of this final action and the advisory action is not mailed until after the end of the three-month shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136 (a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than six months from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran,

can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Shubo (Joe) Zhou/

SHUBO (JOE) ZHOU, PH.D.

PRIMARY EXAMINER